

REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Claim Amendments

Claims 12, 14, 22 and 28-33 were pending in this application when examined.

Claims 12 and 14 are amended to recite a coating composition for medicines, animal drugs, agricultural chemicals, fertilizers or foods, comprising (i) a copolymer and (ii) a solvent. Support for the amendments may be found on page 8, lines 2-19 and page 15, lines 2-18 of the clean version of the substitute specification.

Claims 22, 29, 30, 32 and 33 are amended to correspond with the amendments to claims 12 and 14, and claims 28 and 31 are cancelled in view of the amendments to claims 12 and 14.

Claim Rejections

The Examiner maintains the rejection of claims 12, 30 and 31 under 35 U.S.C. § 102(b) as being anticipated by Hoshi et al. (WO 02/17848; US 2003/0166763); and maintains the rejection of claims 14, 22 and 28 under 35 U.S.C. 102(b) as being anticipated by Hoshi et al.

The Examiner also maintains the rejection of claim 29 under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. (US 4,341,563) in view of Hoshi et al.; maintains the rejection of claim 32 under 35 U.S.C. 103(a) as being unpatentable over Kurihara et al. in view of Hoshi et al.; and maintains the rejection of claim 33 under 35 U.S.C. 103(a) as being unpatentable over Zeidler et al. (US 6,001,391) in view of Hoshi et al.

As applied to the amended claims, Applicants respectfully traverse the rejections.

Claims 12 and 14 have been amended to recite a “composition”, and claim 33 has been amended to recite a “binder”. Under MPEP 2111.02, any terminology in the preamble that limits the structure of the claimed invention **must be treated as a claim limitation**.

Hoshi et al. disclose only a **hard capsule** and a **base material** used for a hard capsule. The capsule and base material are different in physical properties, structure and use from a **coating composition** comprising a copolymer and a solvent, as recited in claims 12 and 14, and a **binder** comprising a copolymer, as recited in claim 33.

Response to Advisory Action

Item A

In item A) of the Advisory Action, the Examiner asserts that “In respect to the arguments in respect to viscosity, one of ordinary skill in the art would interchange methacrylic acid with acrylic acid as those are preferred monomers per the teachings of Hoshi et al.” However, Hoshi et al. does not disclose or suggest the viscosity of the copolymer. As a result, a person of ordinary skill in the art would not have had any reason to interchange methacrylic acid with acrylic acid.

Item B

Furthermore, in item B) of the Advisory Action, the Examiner asserts that “The data is submitted after final rejection and Applicant has not provided any sufficient reason why the evidence was not presented earlier”.

However, the evidence in the Amendment After Final Rejection was presented in response to arguments raised in the final Office Action that “It is easily envisaged to **substitute** the methacrylic acid with acrylic acid as those are the more preferred monomer [0033]” (see page 3, lines 19-21, emphasis added). Thus, Applicants submitted the additional data to explain why methacrylic acid may not simply be “substituted”, as asserted by the Examiner, with acrylic acid in the copolymer of PVA. If methacrylic acid is substituted with acrylic acid in the copolymer of PVA, then the viscosity of the resulting copolymer would **greatly decrease**. Therefore, substituting methacrylic acid for acrylic acid would result in a copolymer having completely different structural properties and features.

Moreover, the chemical structure of methacrylic acid and acrylic acid is different, as shown below.

Methacrylic Acid



Acrylic Acid



A copolymer consisting of methacrylic acid and methyl methacrylate is a completely different product with completely different structural features and properties from a copolymer consisting of acrylic acid and methyl methacrylate, as in claims 12 and 14.

In addition, in item B), the Examiner asserts that evidence of secondary considerations, such as unexpected results or commercial success, is irrelevant to rejections under 35 U.S.C. § 102 (see the sentence bridging pages 2 and 3 of the Advisory Action).

Under MPEP 2131, “A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference”. Moreover, “anticipation under § 102 can be found only **when the reference discloses exactly what is claimed** and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account” (see *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), emphasis added).

Under MPEP 2111.03, the terms “consisting of” and “consist of” exclude any element, step, or ingredient not specified in the claim.

Claims 12 and 14 each recite a composition comprising “a copolymer **consisting of a partially hydrolyzed polyvinyl alcohol** having an average polymerization degree of 300 to 500 and **a polymerizable vinyl monomer** in a weight ratio of 6:4 to 9:1, wherein: the polymerizable vinyl monomer **consists of** acrylic acid and methyl methacrylate combined in a weight ratio of 3:7 to 0.5:9.5 in the copolymer”. Accordingly, the polymerizable vinyl monomer in the copolymer of claims 12 and 14 consists of “acrylic acid and methyl methacrylate”.

The reference does not disclose a copolymer wherein the polymerizable vinyl monomer **consists of “acrylic acid and methyl methacrylate”**, as recited in claims 12 and 14, and thus does not disclose exactly what is claimed. Therefore, the reference does not anticipate claims 12 and 14.

Moreover, as mentioned above, the Examiner takes the position that “It is easily envisaged **to substitute** the methacrylic acid with acrylic acid as those are the more preferred monomers [0033]” (see emphasis added).

Applicants submitted the additional data to explain why methacrylic acid **may not simply be “substituted”**, as asserted by the Examiner, with acrylic acid in a copolymer of PVA. Thus, Applicants have submitted the data in response to the arguments that the components of the reference may be “substituted”. Therefore, the additional data is clearly relevant to address the rejection of record under § 102.

Item C

In item C) of the Advisory Action, the Examiner asserts that the claims do not exclude a partially hydrolyzed polyvinyl alcohol with –SH on the ends (see page 3, line 10).

However, as discussed above, the term “consisting of” excludes any element, step, or ingredient not specified in the claim. Claims 12 and 14 each recite a composition comprising “a copolymer **consisting of a partially hydrolyzed polyvinyl alcohol** having an average polymerization degree of 300 to 500 and **a polymerizable vinyl monomer** in a weight ratio of 6:4 to 9:1, wherein: **the polymerizable vinyl monomer consists of acrylic acid and methyl methacrylate** combined in a weight ratio of 3:7 to 0.5:9.5 in the copolymer”.

PVA-SH is modified version of a polyvinyl alcohol. It has **a terminal thiol group** (i.e., an –SH rather than –OH). On the other hand, claims 12 and 14 recite a copolymer **consisting of** “a partially hydrolyzed polyvinyl alcohol”. The term “consisting of” limits the copolymer to a partially hydrolyzed polyvinyl **alcohol** (–OH), and therefore excludes PVA-SH.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

Applicants’ Further Comments On the Patentability of the Claimed Invention

In addition, Hoshi et al. do not provide any teaching or suggestion regarding a suitable polymerization degree of the polyvinyl alcohol. The reference discloses a **hard capsule** that is made of a PVA-SH copolymer as the base material for the capsule.

Claims 12 and 14 recite **coating compositions** comprising a copolymer consisting of a partially hydrolyzed polyvinyl alcohol “having an average polymerization degree of 300 to 500”, and claim 33 recites a binder comprising a copolymer consisting of a partially hydrolyzed polyvinyl alcohol “having an average polymerization degree of 300 to 500”.

As discussed in the present specification, tablets can be spray-coated with the coating compositions of claims 12 and 14, and the formation of a spider’s thread-like substance can be avoided because the average polymerization degree of the polyvinyl alcohol is “300 to 500” (see, for example, Working Examples 1-5, and Figs. 4-23 on page 185 of the enclosed “Manufacturing Pharmacy” reference).

When the copolymers obtained in Synthetic Examples 2-4 of Hoshi et al. are sprayed onto tablets for coating, a spider’s thread-like substance forms on the tablet, because the copolymers of Hoshi et al. are not suitable as coating compositions, but rather as hard capsules.

As described in manufacturing examples of Hoshi et al., a stainless steel pin is put in and then pulled out to manufacture the hard capsules (see <http://www.capsugel-jp.com/knowledge/process.html>) Applicants enclose several pages from this website and an English translation explaining why spray-coating is not necessary in the reference's hard capsules (please see the steps of "Production of capsule" → "Quality Inspection" → "Selection").

Thus, it is not necessary to avoid the formation of a spider's thread-like substance in the hard capsules of Hoshi et al. by selecting a specific polymerization degree of PVA, as in claims 12 and 14.

Accordingly, the reference fails to disclose a copolymer consisting of a partially hydrolyzed polyvinyl alcohol "having an average polymerization degree of 300 to 500", and provides no reason or rationale to obtain a copolymer having this average degree of polymerization.

Kurihara et al. and Zeidler et al. fail to remedy the deficiencies of Hoshi et al. for the reasons discussed in the Amendment filed February 11, 2011.

Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

Conclusion

For these reasons, as well as the reasons presented in the Amendment filed February 11, 2011, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that the rejections set forth by the Examiner have been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

Makoto NOAMI et al.

By **/Andrew B. Freistein/**
Digitally signed by /Andrew B. Freistein/
DN: cn=/Andrew B. Freistein/, o=WLP,
ou=WLP, email=afreistein@wenderoth.
com, c=US
Date: 2011.05.26 12:58:02 -0400

Andrew B. Freistein
Registration No. 52,917
Attorney for Applicants

ABF/emj
Washington, D.C. 20005-1503
Telephone (202) 721-8200
Facsimile (202) 721-8250
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